

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problems Mailbox.**

THIS PAGE BLANK (USPTO)

PCTWORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 : A61L 2/18, 9/14, A61K 31/045 A61K 9/12		A1	(11) International Publication Number: WO 93/17723 (43) International Publication Date: 16 September 1993 (16.09.93)
(21) International Application Number: PCT/US93/01695		Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>	
(22) International Filing Date: 2 March 1993 (02.03.93)			
(30) Priority data: 844,125 2 March 1992 (02.03.92) US			
(71)(72) Applicant and Inventor: SIMMONS, Paul, L. [US/US]; No. 203, 6250 Kipps Colony Court, Gulfport, FL 33707 (US).			
(74) Agent: FISHER, Arthur, W., III; 5553 West Waters Avenue, Suite 316, Tampa, FL 33634 (US).			
(81) Designated States: AU, BG, BR, CA, DE, DK, GB, HU, JP, KP, KR, NO, RO, RU, SE, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).			

(54) Title: BIODEGRADABLE SURFACE DISINFECTANT**(57) Abstract**

A non-toxic hypocompatible biodegradable surface disinfectant effective against a wide range of pathogenic organisms capable of absorbing and lifting organic matter comprising a composition of interactive constituents including a surfactant, a monohydric alcohol and a polyhydric alcohol in proportion by weight such that the polyhydric alcohol reduces the surface glaze formed by the monohydric alcohol and surface tension formed by water or water-based body fluids enabling the surface disinfectant to kill the pathogenic organisms effectively without deleterious effect to the surface.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	FR	France	MR	Mauritania
AU	Australia	GA	Gabon	MW	Malawi
BB	Barbados	GB	United Kingdom	NL	Netherlands
BE	Belgium	GN	Guinea	NO	Norway
BF	Burkina Faso	GR	Greece	NZ	New Zealand
BG	Bulgaria	HU	Hungary	PL	Poland
BJ	Benin	IE	Ireland	PT	Portugal
BR	Brazil	IT	Italy	RO	Romania
CA	Canada	JP	Japan	RU	Russian Federation
CF	Central African Republic	KP	Democratic People's Republic of Korea	SD	Sudan
CG	Congo	KR	Republic of Korea	SE	Sweden
CH	Switzerland	KZ	Kazakhstan	SK	Slovak Republic
CI	Côte d'Ivoire	LI	Liechtenstein	SN	Senegal
CM	Cameroon	LK	Sri Lanka	SU	Soviet Union
CS	Czechoslovakia	LU	Luxembourg	TD	Chad
CZ	Czech Republic	MC	Monaco	TG	Togo
DE	Germany	MG	Madagascar	UA	Ukraine
DK	Denmark	ML	Mali	US	United States of America
ES	Spain	MN	Mongolia	VN	Viet Nam
FI	Finland				

BIODEGRADABLE SURFACE DISINFECTANT

DescriptionTechnical Field

A non-toxic hypocompatible biodegradable surface disinfectant effective against a wide range of pathogenic 5 organisms.

Background Art

Modern health care facilities are confronted with complex medical problems, whether in the practitioner's office, clinic or large hospital. Such facilities must care for persons with 10 life-threatening diseases while protecting other patients in the same facility without becoming infected. Thus, controlling viral and microbial contamination is a critically important task facing health care facilities today.

In the past, the health care industry believed that 15 sanitation and disinfection applied primarily to emergency rooms and operating rooms or suites. However, today health care provides that chemical sanitation and disinfection is necessary in virtually every area of the modern treatment facility.

20 This awareness has been heightened by the rapid increases in the spread of deadly communicable diseases such as the AIDS virus (HIV), hepatitis and tuberculosis, which has dramatically escalated public awareness for the need of an effective protective means.

25 The need for such protective means applies equally to contaminated surfaces not only to health care facilities but to such environs as public restrooms, telephones, tables and other surfaces contacted by the public.

To this end cleaning compositions with and without a germicide are used on household and public surfaces such as counters, bathroom fixtures, tile surfaces and the like. The cleaning compositions typically include detergents, solvents 5 and other additives such as fragrances. The cleaning compositions are liquids which may be diluted as needed. Other packaging includes aerosol mist, spray, wipes and foams.

Some cleaners include a germicide so that the surface is disinfected. Common disinfecting compounds used in cleaners 10 are the quaternary ammonium compounds, phenols and alcohols.

U.S. 4,689,168 describes a hard surface cleaning composition suitable for glass, chrome, plastic, enamel and other hard surfaces. The composition is applied to the hard surface as an emulsion of an aqueous phase and an oil phase. 15 The bubbling action is caused by the evaporation of volatile constituents from the film or layer of applied compositions, as well as the desire for the aqueous and oil phase components to reform. The bubbling action, characterized by small bubbles of volatile components erupting from the surface of 20 the composition film aids in lifting soil from the hard surface. As an apparent consequence, the rate of cleaning is accelerated. The composition comprises a polar organic solvent or mixture of solvents, a nonvolatile surfactant, a volatile surfactant such as an acetylenic alcohol or diol, a 25 volatile organosiloxane oligomer and water.

U.S. 4,983,317 teaches a liquid composition for cleaning a wide variety of hard surfaces, particularly metallic, plastic, tile, porcelain, glass and mirrored surfaces comprising a polyacrylic acid or a polyacrylate resin builder 30 in combination with a hydrotrope which is an alkali metal salt of a C₂₁ dicarboxylic acid. The organic solvent may be selected from the group consisting of alkylene and polyalkylene glycols of from 2 to 6 carbon atoms and lower alkyl ethers of alkylene and polyalkylene glycols of from 3 to 35 8 carbon atoms, the alkyl ether having from 1 to 4 carbon atoms. A lower aliphatic alcohol of from 2 to 4 carbon atoms may also be included in the composition to adjust evaporation rate of the composition.

U.S. 5,064,635 describes a mixture of one or more surfactants (detergents) with the pH sensitive dye. The surfactant can be diluted with water to give the desired cleaning strength. The surfactant can be an anionic, 5 nonionic, amphoteric or mixtures of the three types. Typical anionic surfactants used are petroleum sulfonates, such as sodium dodecylbenzene sulfonate, alcohol sulfates such as sodium lauryl sulfate and ethoxylated higher fatty alcohol sulfates such as sodium lauryl ether sulfate. Typical 10 nonionic surfactants are primary alcohol ethoxylates, secondary alcohol ethoxylates, alkyl phenol ethoxylates and alkanolamides. The amphoteric surfactants include a number of types of carboxylates derived from fatty imidazolines such as sodium dicarboxyethylcoco phosphoethyl imidazoline or fatty 15 propionate such as cocoamphopropionate or cocoamphodipropionate. The composition of a basic cleaner includes the surfactant or mixture of surfactants at about 0.1 percent to about 20.0 percentage by weight. This range of surfactant is for usage in a nondiluted product for household 20 use. Thymolphthalein in the range of about 0.01 percent to about 1 percent by weight will give a broad range of blue color when varying intensity using an alkali system to adjust the pH of the composition.

U.S. 4,965,063 and U.S. 5,057,303 teach compositions 25 similar to U.S. 5,064,635.

U.S. 4,329,334 shows a homogeneous liquid anionic-amphoteric based antimicrobial conditioning shampoo which includes about 0.5 to 2.5 percent of the antimicrobial agent, 1-imidazolyl-1-(4-chlorophenoxy)-3, 3-dimethylbutan-2, 30 one, solubilized in an aqueous solution of critical amounts of a mixture of the following specific ingredients: about 10-40 percent by weight of an anionic sulfate or sulfonate surface active agent; about 0.1-7.5 percent by weight of an amphoteric surfactant selected from the group consisting of cocobetaine, 35 cocosulfobetaine, cocoamidopropylbetaine, cocoamidopropylsulfobetaine or combinations thereof; a nonionic surface active agent selected from the group

consisting of a tertiary amine oxide, a polyoxyethylene hexitan mono-higher fatty acid ester and mixtures thereof; and about 0.5-2 percent by weight of a lower aliphatic monohydric or polyhydric alcohol or mixtures thereof in certain critical 5 amounts to avoid precipitation of the antimicrobial agent.

U.S. 3,654,165 teaches a cleaner-sanitizer for use on telephone instruments including a fast-acting, penetrative, quick-drying bacteriocidal detergent solution which leaves a safe, active residue of selected proportions of sodium lauryl 10 sulfate, dimethyl sulfone, isopropanol and iodine in solution.

U.S. 4,793,988 describes a composition for disinfecting a surface, such as a public restroom facility or telephone. The composition and delivery of the composition provides for the placement of a thin layer of disinfectant including a dye.

15 The dye disappears as the thin layer effects the germicidal activity of the disinfectant. A sample of the germicidal composition was prepared with 400 mg of sodium dodecyl sulfate (SDS), 400 mg of octyl phenoxy polyethoxyethanol marketed as Triton X-100 and 100 mg of blue dye thymophthalein. This 20 composition was tested for germicide effectiveness against Herpes simplex virus type 2, Neisseria gonorrhoeae, Staphylococcus aureus, Escherichia coli O11K58, Shigella sonnei, Salmonella typhimurium and Candida albicans.

U.S. 4,975,217 describes germicidal compositions for 25 direct application to human skin including an organic acid, e.g., malic acid, and an anionic surfactant, e.g., a sodium alpha-olefin sulfonate, as active ingredients, and can optionally include an alcohol, e.g., specially denatured ethyl alcohol, as an additional active ingredient. When formulated 30 as soaps and lotions, the compositions have been found to produce more than a 2.0 log reduction in bacteria applied to skin. Organic acids and anionic surfactants, e.g., malic acid and a sodium alpha-olefin sulfonate surfactant, are used as active ingredients in germicidal products which are applied 35 directly to the skin, such as hand-washing soaps, skin-care lotions, soapy-lotions, or wipes containing these materials. Optionally, the products can include an alcohol, such as,

specially denatured ethyl alcohol, ethyl alcohol and isopropyl alcohol as an additional active ingredient. These formulations, in addition to killing viruses, also effectively kill bacteria and yeasts. In particular, the 5 formulations have been found to kill a variety of microorganisms both in vitro experiments performed in test tubes and, even more importantly, in in vivo experiments performed on human hands. Moreover, notwithstanding their germicidal activity, the formulations have been found to be 10 non-irritating to human skin.

U.S. 4,046,706 shows a composition for cleaning contact lenses comprising a poly(oxyethylene)-poly(oxypropylene) block copolymer having a molecular weight between 1900 and 15,500, a water solubility in excess of about 10 gms per 100 ml, a cloud 15 point in 1 percent aqueous solutions above about 30 degrees C, and a foam height in excess of 30 mm; a microbial growth inhibitor; ethyl or isopropyl alcohol; an amphoteric surfactant and water.

U.S. 3,578,499 teaches a powder composition containing a 20 gelling agent, a neutral diluent, a wetting agent and a dye or coloring additive. The powder gelling composition when added to water forms a gel. Acid or alkaline materials are added for cleaning, biocidal agents for sanitizing or other materials to produce a desired effect. The significant 25 advantage of this method is the increased residence time and hence contact time between agents in the gel and the surface to be acted on. A third component included in the gelling composition is a wetting agent exemplified by a linear alkyl benzene sulfonate type material wherein the alkyl group may 30 include from about 12 to 14 carbon atoms. The wetting agent should be desirably characterized as a anionic agent although it is recognized that nonionic surfactants may also be employed. One wetting agent found useful herein is the commercially available sulfonate of dodecylbenzene.

35 U.S. 2,333,124 describes a method for sterilizing air laden with bacteria or other pathogenic organisms comprising contacting the air with a mixture of glycols in vapor form in

proportions to provide about 1 gram of such glycols in vapor form to not more than about 5 to 7 million cubic centimeters of air.

U.S. 2,857,315 shows a stable anti-perspirant stick
5 having a base comprising a sodium stearate-propylene glycol soap gel having an active anti-perspirant agent sodium zirconium lactate. The sodium stearate-propylene glycol soap gel may contain alcohol in an amount not substantially greater than the propylene glycol by weight.

10 Various spray germicides for sanitizing such surfaces is typified by in U.S. 3,445,564. U.S. 3,445,564 is directed to a method, compositions and articles for sanitizing public or communal facilities prior to individual use. The method consists of applying a thin layer of a rapidly drying liquid
15 germicidal composition to a surface such as a toilet seat.

The rapidly drying germicidal compositions consist essentially of a lower eliphatic alcohol and at least about 5 percent of a volatizing agent therefor, such as acetone. Isopropyl alcohol has excellent germicidal activity and sufficiently volatile to
20 give a satisfactory drying rate when blended with suitable proportions of a volatizing agent. In as much as the lower eliphatic alcohols are not sufficiently volatile to afford usefully short drying times for practical purposes in the method and articles of the Kirschner invention it was
25 necessary to include a volatizing agent in the germicidal composition.

The proportion of volatizing agent to lower aliphatic alcohol in the rapidly drying germicidal compositions employed in the invention may vary widely depending upon a number of
30 factors, which include among others, the volatility of the alcohol employed, the volatility of the volatilizing agent, the desired drying rate of the germicidal composition, the amount of germicidal agent applied to the surface to be treated and the method of application of the germicide, not to
35 mention the prevailing conditions of temperature and relative humidity under which the product is to be employed.

Although the isopropyl alcohol-acetone composition of U.S. 3,445,564 has germicidal activity against bacteria, fungi and other lower organisms, additional antibacterial, antifungal or other active ingredients may be incorporated to enhance the overall germicidal effectiveness. Suitable germicidal additives include the well known antibacterial quaternary ammonium compound. In essence, U.S. 3,445,564 teaches the use of isopropyl alcohol to kill a limited number of germs on a dry toilet seat with the addition of acetone to volatize an already highly volatile chemical to rapidly dry the toilet seat for use within 30 seconds.

The use of a dye in a bacteracidal solution as disclosed in U.S. 2,449,274 is employed to provide a visual indication of the effectiveness of such sprays.

U.S. 4,678,658 shows an aerosol spray for use in disinfecting a surface for personal use such as a public restroom facility or telephone. The composition and delivery of the compositions provides for the placement of a spray of disinfectant which includes a dye that disappears as the spray effects the germicidal activity of the disinfectant. The composition is also rapidly drying, so that the dye disappears as well as the disinfecting composition leaving the surface dry. However, the spray is corrosive and environmentally unsafe.

U.S. 3,821,413 discloses a formulation of materials which permits an effective, uniform rate of evaporation of glycols from an air circulator device to reduce airborne bacteria in the surrounding atmosphere. It was observed that the relative amounts and identities of the components of the invention are critical to the attainment of the desired continuous evaporation of glycols over a prolonged period of time.

The composition of U.S. 3,821,413 is a single phase liquid composition especially adapted for volatilization at a substantially uniform rate from the air circulator device.

Generally speaking, the composition includes three essential components (1) a glycol, (2) an organic polar coupling compound for maintaining the homogeneity prevents the glycol

from separating from the mixture during evaporation of the mixture into the atmosphere and (3) an organic, relatively non-polar compound for forming hydrophobic micelles with the glycol molecules in the resulting mixture for reducing the 5 affinity of the glycol to atmospheric moisture and thereby increasing the rate at which the glycol may be evaporated into the atmosphere.

The composition contains the glycol germicide. If desired, other suitable germicides or antiseptic agents can be 10 added provided, however, that the glycol concentration of the composition does not fall below 5 percent by weight of the total mixture. Such germicides include quaternary ammonium compounds, phenols, bisphenols, salicylanilides, carbanilides, formaldehyde and chloride.

15 The required glycol evaporation rate for attaining the desired air sanitizing performance depends on the satisfactory stability and uniform nature of the liquid composition during evaporation from the mixture. Accordingly, the compositions of the invention include from about 2 percent to about 40 20 percent by weight of an organic polar coupling compound for maintaining the homogeneity of the mixture to prevent the glycol from separating from the mixture during the evaporation process.

25 The affinity of glycols to attract atmospheric moisture significantly reduces their volatility and impairs their evaporation rate. Accordingly, the compositions of the invention include from about 5 percent to about 80 percent by weight of an organic, relatively non-polar compound for forming hydrophobic micelles surrounding the glycol molecules 30 in the mixture for reducing the affinity of the glycol to atmospheric moisture and thereby increase the rate of evaporation of the glycol. Without this micelle formation, it was found that the glycol or mixture of glycols in the mixture cannot evaporate appreciably in an air circulator device 35 containing a wick immersed in the liquid composition.

U.S. 3,806,593 is directed to an acne treatment medication applied to the skin for preventing the formation of

acne or decreasing already established acne. An important factor for the occurrence of acne is the presence of bacteria in the sebaceous glands in the skin. It is known that the bacteria in the sebaceous glands form esterases which 5 hydrolyze the sebum fats to alcohols and free fatty acids.

The medicinal acne-preventing or acne-diminishing composition of U.S. 3,806,593 is based on the bacterial esterase activity in the sebaceous glands which together with the water already present in the skin can hydrolyze an ester 10 having a good penetration capacity into the sebaceous glands to form one and preferably two antibacterially active components, viz. an acid and an alcohol, which are harmless to the skin. The active compound in the composition is one or more esters chosen from the group consisting of ethyl lactate, 15 isopropyl lactate and/or glycerol mono or dilactate. The esters hydrolyze in the sebaceous glands due to the esterases present in the glands to form the corresponding acids and alcohols. Lactic acid and the lower alcohols and also glycerol to a certain extent exert a good 20 antibacterial activity when formed in situ in the sebaceous glands. The esters are lipophilic and can thus penetrate into the said glands. Even if a beneficial action can be achieved by application of the ester or esters per se, it has been found to be suitable to apply the ester in the form of a 25 solution in ethyls alcohol or isopropyl alcohol. The alcohol prevents hydrolysis of the ester already in the composition, the alcohol moves the hydrolysis equilibrium towards ester formation. The alcohol can also facilitate the penetration of the ester into the skin.

30 As is well-known alcohol in high concentrations may cause a drying-out of the skin. To counteract this effect, the composition may include a moisture-retaining agent such as a lower, suitably water-free polyol, viz. propylene glycol or glycerol. The content of propylene glycol or glycerol in the 35 composition according to the invention may be up to 25 percent, suitably not more than 10 percent by weight and preferably 1-5 percent. High levels of polyol tend to make

the composition smears upon application on the skin and should thus be avoided.

The preferred composition according to the invention consists of about 15 percent by weight of ethyl lactate, about 5 2 percent by weight of propylene glycol, the remainder being ethyl alcohol.

In summary, U.S. 3,806,593 relates to acne medication comprising esters that hydrolyze in the sebaceous glands in combination with an alcohol to prevent hydrolysis of the 10 esters as well facilitate the penetration of the ester into the skin, and propylene glycol or glycerol to prevent drying of the skin. The preferred ration of the constituents is 15 percent to 83 percent to 2 percent respectively.

U.S. 4,664,909 discloses a stable, fast drying pituitous 15 powder deodorant suspension in an alcohol media containing a minimal amount of water and a critical amount of the essential hydroxyethyl cellulose as the suspending agent.

The fast drying pituitous suspension of particulate material in an aqueous alcohol media contains hydroxyethyl 20 cellulose at levels above its normal solubility limit by polyhydric.

More specifically, U.S. 4,664,909 relates to stable pituitous suspensions of particulate material, preferably about 1-20 percent, uniformly suspended in alcohol/aqueous 25 media containing a high alcohol content and a lower water content. The alcohol media may be a lower monohydric alcohol selected from the group consisting of methanol, ethanol, isopropanol and mixtures thereof. The use of polyhydric alcohols such as propylene glycol, butylene glycol and polyols thereof, and glycerin decreases the critical water level required in the hydroxyethyl cellulose-containing alcohol media.

It has been unexpectedly found that powders can be suspended in alcoholic/aqueous media containing a high alcohol content and a lower water content by using the water soluble polymer hydroxyethyl cellulose at critical levels above its ethanol solubility range which may be broadened by specified

polyhydric alcohols. This polymer is unique in its property to form stable suspensions.

Specifically, polyhydric alcohols can be partially substituted for the monohydric alcohol, not to exceed the 5 monohydric alcohol content. The monohydric alcohol content, such as ethanol, must exceed the upper solubility level for the water soluble polymer hydroxyethyl cellulose in ethanol or other lower alkanol. The reported upper solubility level of this water soluble polymer in ethanol is 70 percent. Below 10 this level and within normal soluble use ranges, a uniformly viscous liquid is obtained which pours evenly. Although, it appears aesthetically desirable, it will not support suspended powder and segregation occurs. However, at ethanol 15 concentrations above its solubility range, the polymer becomes less soluble and forms the desired pititious type liquid. If ethanol is further increased resulting in very low water levels the polymer will precipitate out and its suspending properties are again lost. Accordingly, a 70:30 ration of ethanol-water is optimim. However, it was found that this 20 problem can be eliminated by the sufficient addition of a polyhydric alcohol such as glycerine, propylene glycol, butylene glycol and polyglycols thereto.

Accordingly, it has been found that the monohydric alcohol constitutes about 55-85 percent; and the water content 25 may be as low as 5 percent if at least 10 percent polyhydric alcohol is also present in the suspension. The combined water and polyhydric alcohol content is at least 15 percent and may be up to about 25 percent. Thus, it is apparent that the proportions of monohydric alcohol, water and polyhydric 30 alcohol are interdependent.

In summary, U.S. 4,664,909 teaches a fast-drying deodorant comprising a critical amount of hydroxyethyl cellose as the deodorant to encapsulate or isolate bacteria to prevent growth of the bacteria, suspended in a solution of monohydric 35 alcohol to provide the fast drying characteristics and polyhydric alcohol to improve the overall soluability of the solution to allow the use of increased levels of monohydric

alcohol. The relative proportions of the monohydric alcohol, water and polyhydric alcohol are driven or determined by the desired solubility and therefore are interdependent.

5 U.S. 3,821,413 teaches a disinfectant consisting of propylene glycol to stabilize the composition and retard evaporation. This disinfectant is toxic, corrosive and non-biodegradable.

10 U.S. 3,966,902 disclosed various polymer complex carriers such as propylene glycol for use with an active ingredient such as a disinfectant or fragrance.

U.S. 4,690,779 refers to the use of propylene glycol in combination with alcohol and fragrances. This composition is both toxic and non-biodegradable.

15 U.S. 4,209,500 teaches a composition suitable for use in aerosol sprays including an anhydrous alcohol and fragrance or perfume. This composition is corrosive, non-biodegradable and non-evaporative.

Additional examples of the prior art are found in U.S. 580,213, U.S. 3,282,776, U.S. 4,201,764, U.S. 4,282,179, U.S. 20 4,265,899, U.S. 4,283,421, U.S. 4,364,515, U.S. 4,550,105, U.S. 4,105,431, U.S. 4,243,403, U.S. 4,278,206, U.S. 4,322,475, U.S. 4,436,732, U.S. 4,464,293, U.S. 4,597,887, U.S. 4,252,694, U.S. 4,279,762, U.S. 4,325,201, U.S. 4,540,505, U.S. 4,675,397 and U.S. 4,915,934.

25 Examination of the prior art reveals most existing disinfectants available are either toxic or non-biodegradable or both. Toxic chemicals that are not biodegradable contaminate our environment, the soil and the water supply.

30 In recognition of the dangers of existing disinfectants, health facilities are required to notify employees that toxic chemicals are in use and advise them of the possible hazards that result or could result as a consequence of misuse or a spills. Such notices must also be given to the community at large.

35 Other laws and regulations require users to document the use of toxic chemicals and require that the excess, the waste, or the residue be collected and properly stored. These

5 materials must be collected by licensed and approved toxic waste companies, taken to an authorized disposal site and legally destroyed. The cost of disposing of such toxic material is often more expensive than the initial purchase price.

Simply stated, the prior art fails to teach or suggest an effective non-toxic hypocompatible biodegradable surface disinfectant for application on contaminated surfaces.

10 Disinfectants today should be non-toxic and biodegradable and capable of killing or inactivating both pathogenic organisms. Further, such disinfectants should be chemically compatible with the numerous surfaces found in modern healthcare facilities.

15 As described more fully hereinafter the instant invention is directed to an environmentally safe surface disinfectant capable of killing anaerobic and aerobic bacteria, viruses including the HIV virus, mildew, mold and fungus. The principal active anti-microbial, anti-viral ingredients of the invention are selected from a group of monohydric alcohols and 20 polyhydric alcohols.

25 In the past such alcohols have had limited use outside the laboratory due to various undesirable characteristics of alcohol. For example, it has been universally accepted that alcohol has very limited application as a widely used disinfectant because alcohol is unable to penetrate protein rich material, evaporates quickly, has limited stability and shelf life, has a pungent odor and tends to form a glaze on hard surfaces possibly hiding or covering visible contamination.

30 The instant invention has evolved from an extensive development program involving the unexpected formulation of certain chemicals to reduce or inhibit those undesirable features of alcohol and to make alcohol safe and effective for use outside the laboratory.

35 Disclosure of the Invention

The present invention relates to a non-toxic hypocompatible biodegradable surface disinfectant for

application to inanimate surfaces to kill a wide range of pathogenic organisms.

The surface disinfectant comprises a composition including an anionic, nonionic or cationic surfactant or mixture thereof, a monohydric alcohol and a polyhydric alcohol. The anionic surfactants may be selected from the group consisting of petroleum sulfonates, such as sodium dodecylbenzene sulfonate, alcohol sulfates such as sodium lauryl sulfate and ethoxylated higher fatty alcohol sulfates such as sodium lauryl ether sulfate and the like. The nonionic surfactant may be selected from the group consisting of primary alcohol ethoxylates, secondary alcohol ethoxylates, alkyl phenol ethoxylates, alkanolamides and the like. The cationic surfactant may be selected from the group consisting of cetylpyridinium, methylbenzethonium chloride, dodecylamine, hexadecylamine, hexadecylamine hydrochloride, dodecylaniline, oleylmethylamine, ethylenediyethylamine, methyl sulfate, oleylbenzylaminoethylenediyethylamine hydrochloride, sulfate of lauryl pyridinium, octadecyl- methylenepyridinium acetate, methyl sulfate of dimethyloctadecylsulfonium, betaine compound of diethyl- aminoacetic acid and octadecylchloromethyl ether and the like. The monohydric alcohol is selected from the group consisting of isopropyl, methyl, ethyl, n-propyl, n-butyl, tert-butyl alcohol or allyl alcohol and/or mixtures thereof. The polyhydric alcohol is selected from the group consisting of propylene glycol; 1,3 propanediol; 1,2 butanediol, PEG 400; glycerol or 1,4 butanediol and/or mixtures thereof.

The proportion by weight is such that the polyhydric alcohol reduces the surface glaze formed by the monohydric alcohol and surface tension formed by water or water-based body fluids enabling the germicide to kill the pathogenic organisms and act equally effective on a patient or inanimate surface without deleterious effect to either.

The monohydric alcohol provides the primary disinfecting or killing effect on the pathogenic organisms; while, the polyhydric alcohol lowers the flash point of the composition

and soothes the skin. The polyhydric alcohol also slows the rate of evaporation, reduces or eliminates the intersurface glazing effect of monohydric alcohol and homogenizes the interactive ingredients.

5 The relative proportions by weight of interactive ingredients chemically reduces the tensile strength of the surface liquids on the surface permitting the surface disinfectant effect to act directly on the pathogenic organisms.

10 The non-toxic hypocompatible biodegradable surface disinfectant in liquid form may be dispensed in various delivery systems including spray, foam, pour and squirt for a aerosol or non-aerosol product. Alternate systems may include a towelette or an absorbent wipe containing the product in an 15 airtight enveloping material such as sealed foil or other wrapping material could be used for a single application.

The invention accordingly comprises the features of construction, combination of elements, and arrangement of parts which will be exemplified in the construction 20 hereinafter set forth, and the scope of the invention will be indicated in the claims.

Best Mode for Carrying Out the Invention

Numerous surface disinfectant compositions and delivery devices have been developed to kill various pathogenic 25 organisms. The wide range of application or use is limited by the chemical and biological effect of such compositions on the various surfaces and delivery means exposed to such compositions.

The present invention relates to a non-toxic 30 hypocompatible surface disinfectant for application on hard surfaces such as floors, restrooms or tables effective against a wide range of pathogenic organisms such as bacteria including staphylococcus aureus, pseudomonas aeruginosa and salmonella coleraesuis and viruses including HIV-I, HIV-II, 35 tuberculosis, polio and herpes simplex type 2 as well as fungi (trichophyton mentagrophytus), mold, mildew and spores through alternate delivery means.

The surface disinfectant comprises a non-toxic hypocompatible biodegradable composition of selected surfactants, selected monohydric alcohols, selected polyhydric alcohols and inert ingredients combined in relative proportions by weight to disinfect various surfaces through direct application without deleterious effect to the surfaces to be disinfected.

5 The surfactant may be anionic, nonionic or cationic or mixtures thereof. The anionic surfactant may be selected from the group consisting of petroleum sulfonates, such as sodium dodecylbenzene sulfonate, alcohol sulfates such as sodium lauryl sulfate and ethoxylated higher fatty alcohol sulfates such as sodium lauryl ether sulfate and the like. The nonionic may be selected from the group consisting of primary 10 alcohol ethoxylates, secondary alcohol ethoxylates, alkyl phenol ethoxylates, alkanolamides and the like. The cationic may be selected from the group consisting of cetylpyridium, 15 methylbenzethonium, chloride, dodecylamine, hexadecylamine, hexadecylamine hydrochloride, dodecyl aniline, oleyl 20 methylamine ethylene diethylamine methyl sulfate, oleyl benzylamino ethylene diethyamine hydrochloride, sulfate of lauryl pyridinium, octadecyl methylene pyridinium acetate, methyl sulfate of dimethyloctadecyl sulfonium, betaine 25 compound of diethyl aminoacetic acid and octadecyl chloromethyl ether and the like.

The monohydric alcohol is selected from the group consisting of isopropyl, methyl, ethyl, n-propyl, n-butyl, tert-butyl or allyl or mixtures thereof.

30 The polyhydric alcohol is selected from the group consisting of propylene glycol; 1,3 propanediol; 1,2 butanediol, PEG 400; glycerol or 1,4 butanediol or mixtures thereof.

35 As used herein, the term non-toxic refers to the requirements of the LD 50 Oral Toxicity Test; that is, non-toxic, non-poison, to rate at 50 times the lethal dose.

As used herein, the term biodegradable refers to decomposition in the presence of 25 percent organic material

within 90 days at 69 degrees F (Standard Temperature) with moisture content of 100 parts per million.

As used herein, the term challenge refers to a test colony or specimen of 10^6 specified pathogenic organisms.

As used herein, the term hypocompatible shall mean no material degradation efforts associated with surfaces to include, for example, discoloration, corrosion, cracking, crazing and embrittlement.

The specific monohydric alcohols and polyhydric alcohols and relative ratios thereof optimize the particular characteristics of solubility, specific gravity, conductivity, pH, flash point, boiling point and evaporation essential to the effective use of the instant germicide against the challenge as defined herein on pathogens as described herein with a nontoxic effect as defined herein on patients, and with a hypocompatible effect as defined herein on the surfaces described herein.

Specifically, the presence of the polyhydric alcohol raises the boiling point of the surface disinfectant slowing the rate of evaporation of the surface disinfectant. As a solvent, the polyhydric alcohol prevents the tendency of monohydric alcohol to form a glaze on the target surface that masks the pathogenic organisms and breaks the barrier formed by surface tension of water and water-based body fluids enabling the surface disinfectant to act on the pathogens more rapidly. In addition, the polyhydric alcohol serves as an emulsifier to assure that the composition remains homogenized during storage and use.

Further, the polyhydric alcohol reduces the harmful effects of monohydric alcohol if swallowed or sprayed into the eyes or on mucus membranes as well as soothing the skin upon contact. Since the polyhydric alcohol reduces toxicity to human cells the need to dilute the surface disinfectant has been eliminated. Polyhydric alcohol also acts as a secondary disinfectant useful to disinfect air. In the preferred percentage used, tests indicate that the polyhydric alcohol increases the overall effectiveness of the germicide against most viruses, mold and mildew.

Since the surface disinfectant was developed for use on a wide variety of surfaces and dispensed from a number of dispensing modes or means of dispersant materials the measure of chemical resistance is important to permit broad use and application. To be effective, the surface disinfectant must be hypocompatible with CPVC, Epoxy, Polypropylene, PVC, Cyolac (ABS), Phenolic, Nylon, Noryl, Delrin (Acetal), Ryton to 200°F, Kynar, Teflon, Stainless Steel 316, Stainless Steel 304, Carpenter 20, Stainless steel (440), Titanium, Cast Bronze, Cast Iron, Aluminum, Hastelloy C, Carbon/ceramic, Ceramagnet A, Viton, Buna N., Neoprene, Nitrile, Natural rubber, Hypalon, EPDM, Kel-F, Tygon, Silicone, Ceramic and Carbon/graphite.

Comparative results of the surface disinfectant with the individual constituents have demonstrated that the combination of interactive ingredients provides a germicide effective against an expansive range of materials found in a wide variety environments through various delivery means such as aerosol, pump, spray or swab without degradation of the materials.

In order to accomplish the design criteria of a non-toxic, hypocompatible, biodegradable surface disinfectant effective against the wide range of pathogenic organisms described herein, the composition should have a pH of between about 7 and 5, virtually evaporate before about 6 and 20 minutes to have an effective kill time of about 8 to 12 minutes and prevent surface residue, a specific gravity of about .85, viscosity below 4 and relatively no conductivity.

The effective proportional relationship of the ingredients by weight for the surfactant as described herein is about between 0.005 and 1.0, for the monohydric alcohol as described herein is between about 65 percent to 75 percent and for the polyhydric alcohol as described herein is between about 4 percent and 16 percent.

The most preferred proportional relationship of the active ingredients by weight is about 70 percent for the monohydric alcohol and between 8 to 12 percent for the

polyhydric alcohol. The preferable amount of polyhydric alcohol is 6 to 14 percent by weight. Less than 4 percent of polyhydric alcohol by weight does not provide adequate kill and exhibits an excessive alkaline pH; while, more than 16 percent of polyhydric alcohol by weight leaves a residue to attract and harbor pathogens. This surface disinfectant is capable of absorbing and lifting 25 percent (by weight) of organic matter relative to the weight of the surface disinfectant.

10 It will thus be seen that the objects set forth above, among those made apparent from the preceding description are efficiently attained and since certain changes may be made in the above construction without departing from the scope of the invention, it is intended that all matter contained in the 15 above description or shown in the accompanying drawing shall be interpreted as illustrative and not in a limiting sense.

It is also to be understood that the following claims are intended to cover all of the generic and specific features of the invention herein described, and all statements of the 20 scope of the invention which, as a matter of language, might be said to fall therebetween.

Now that the invention has been described,

Claims

1. A non-toxic hypocompatible biodegradable surface disinfectant effective against a wide range of pathogenic organisms comprising a composition including an anionic, 5 nonionic or cationic surfactant or mixtures thereof, a monohydric alcohol in proportion by weight such that said polyhydric alcohol reduces the surface glaze formed by said monohydric alcohol and surface tension formed by water or water-based body fluids enabling said germicide to kill the 10 pathogenic organisms and act effectively on inanimate surfaces without deleterious effect.

2. The non-toxic hypocompatible biodegradable surface disinfectant of Claim 1 wherein said anionic surfactant may be selected from the group consisting of petroleum sulfonates, 15 such as sodium dodecylbenzene sulfonate, alcohol sulfates such as sodium lauryl sulfate and ethoxylated higher fatty alcohol sulfates such as sodium lauryl ether sulfate and the like.

3. The non-toxic hypocompatible biodegradable surface disinfectant of Claim 1 wherein said nonionic surfactant may 20 be selected from the group consisting of primary alcohol ethoxylates, secondary alcohol ethoxylates, alkyl phenol ethoxylates, alkanolamides and the like.

4. The non-toxic hypocompatible biodegradable surface disinfectant of Claim 1 wherein said cationic surfactant may 25 be selected from the group consisting of cetylpyridium, methylbenzethonium, chloride, dodecylamine, hexadecylamine, hexadecylamine hydrochloride, dodecyl aniline, oleyl methylamine ethylene diethylamine methyl sulfate, oleyl benzylamino ethylene diethyamine hydrochloride, sulfate of 30 lauryl pyridinium, octadecyl methylene pyridinium acetate, methyl sulfate of dimethyloctadecyl sulfonium, betaine compound of diethyl aminoacetic acid and octadecyl chloromethyl ether and the like.

5. The non-toxic hypocompatible biodegradable surface disinfectant of Claim 1 wherein said monohydric alcohol is selected from the group consisting of isopropyl, methyl, ethyl, n-propyl, n-butyl, tert-butyl or allyl or mixtures 5 thereof.

6. The non-toxic hypocompatible biodegradable surface disinfectant of Claim 1 wherein said polyhydric alcohol is selected from the group consisting of propylene glycol; 1,3 propanediol; 1,2 butanediol, PEG 400; glycerol or 1,4 10 butaneidiol or mixtures thereof.

7. The non-toxic hypocompatible biodegradable surface disinfectant of Claim 1 including about 0.005 percent to 1.0 percent of said surfactant by weight.

8. The non-toxic hypocompatible biodegradable surface 15 disinfectant of Claim 1 including about 65 percent to 75 percent of said monohydric alcohol by weight.

9. The non-toxic hypocompatible biodegradable surface disinfectant of Claim 1 including about 4 percent to 16 percent of said polyhydric alcohol by weight.

20 10. The non-toxic hypocompatible biodegradable surface disinfectant of Claim 1 including preferably about 6 percent to 14 percent of said polyhydric alcohol by weight.

11. The non-toxic hypocompatible biodegradable surface 25 disinfectant of Claim 1 including most preferably about 8 percent to 12 percent of said polyhydric alcohol by weight.

12. The non-toxic hypocompatible biodegradable surface disinfectant of Claim 1 including about 70 percent of said monohydric alcohol by weight.

13. The non-toxic hypocompatible biodegradable surface disinfectant of Claim 12 including about 10 percent of said polyhydric alcohol by weight.

14. The non-toxic hypocompatible biodegradable surface disinfectant of Claim 1 including 0.005 percent to 1.0 percent of said surfactant by weight, including about 65 percent to 75 percent of said monohydric alcohol by weight and about 8 percent to 12 percent of said polyhydric alcohol by weight.

15. The non-toxic hypocompatible biodegradable surface disinfectant of Claim 1 including about 0.1 percent of said surfactant by weight, including about 70 percent of said monohydric alcohol by weight and about 10 percent of said polyhydric alcohol by weight.

16. A non-toxic hypocompatible biodegradable surface disinfectant for use against a wide range of pathogenic organisms comprising a homogenous composition of interactive constituents including about 0.1 percent surfactant by weight, including about 70 percent of a monohydric alcohol and about 10 percent of a polyhydric alcohol by weight such that said polyhydric alcohol reduces the surface glaze formed by said monohydric alcohol and surface tension formed by water or water-based body fluids enabling said surface disinfectant to rapidly contact the pathogenic organisms and act on the inanimate surface without deleterious effect.

25 17. A biodegradable surface disinfectant effective against a wide range of pathogenic organisms comprising a composition including a surfactant from the group consisting of anionic, nonionic or cationic or mixtures thereof, including a monohydric alcohol from the group consisting of 30 isopropyl, methyl, ethyl, n-propyl, n-butyl, tert-butyl or allyl or mixtures thereof, a polyhydric alcohol from the group consisting of propylene glycol; 1,3 propanediol; 1,2 butanediol, PEG 400; glycerol or 1,4 butanediol or mixtures

thereof, and a surfactant in proportion by weight such that said polyhydric alcohol reduces the surface glaze formed by said monohydric alcohol and surface tension formed by water or water-based body fluids enabling said surface disinfectant to
5 kill the pathogenic organisms on inanimate surfaces without deleterious effect thereto.

18. The biodegradable surface disinfectant of Claim 17 including about 0.1 percent to 1.0 percent of said surfactant by weight, including about 65 percent to 75 percent of said
10 monohydric alcohol by weight, about 8 percent to 12 percent of said polyhydric alcohol by weight and about 2 percent to 4 percent of said surfactant by weight.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US93/01695

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) : A61L 2/18, 9/14; A61K 31/045, 9/12
 US CL : 424/47, 45, 76.8; 514/975; 422/28

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 424/47, 45, 76.8; 514/975; 422/28; 424/76.1, 76.2

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data-base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US, A, 4,511,486 (SHAH) 16 APRIL 1985 Column 1, lines 66-68, column 2, lines 22-35, column 3, lines 5-7, 35.	1-18

Further documents are listed in the continuation of Box C. See patent family annex.

- * Special categories of cited documents:
- *A* document defining the general state of the art which is not considered to be part of particular relevance
- *E* earlier document published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed
- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- *&* document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
26 APRIL 1993	02 JUL 1993
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer EDWARD J. WEBMAN <i>Edward J. Webman</i> for
Facsimile No. NOT APPLICABLE	Telephone No. (703) 308-2351

Form PCT/ISA/210 (second sheet)(July 1992)★